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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,374	03/29/2007	Kyu Chan Kwon	CMT0034US	9097

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CANTOR COLBURN LLP
20 Church Street
22nd Floor
Hartford, CT 06103

EXAMINER

DEBERRY, REGINA M

ART UNIT	PAPER NUMBER
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1647

NOTIFICATION DATE	DELIVERY MODE
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05/20/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptopatentmail@cantorcolburn.com

Office Action Summary	Application No. 10/560,374	Applicant(s) KWON ET AL.	
	Examiner REGINA M. DEBERRY	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7 and 9-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7 and 9-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05 February 2010 has been entered.

Status of Application, Amendments and/or Claims

The amendment and Applicant's arguments, filed 08 January 2010, have been entered in full. Claims 6 and 8 are canceled. Claims 1, 3, 4, 9 are amended. Claims 1-5, 7, 9-11 are under examination.

Claim Rejections-35 USC § 102(e)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 7, 9-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Vukmirovic et al. (Reference of record; WO 2004/006958 A1). The basis for this rejection is set forth at pages 2-4 of the previous Office Action (09 November 2009).

Vukmirovic et al. teach aqueous pharmaceutical compositions comprising erythropoietin (EPO) (abstract, page 3, 3rd paragraph; page 6 and claims). Vukmirovic et al. teach all forms of EPO including recombinant EPO (page 6-7; **applies to claim 2**). Vukmirovic et al. teach concentrations of EPO from 1000 IU/ml to 100,000 IU/ml (page 7 and claims; **applies to claim 11**). Vukmirovic et al. teach buffering agents in the range of 1 mM-50 mM and a pH between 6-8 (page 7 and claims; **applies to claim 10**). Vukmirovic et al. teach *water-soluble inorganic salts* (sodium chloride and calcium chloride) and *buffering reagents* (phosphate and citrate buffers). Vukmirovic et al. teach *polyhydric alcohols* (polysorbate 20, polysorbate 80, polyethylene glycol, glycerol, poloxamer polyol and polyhydric alcohol), water-soluble inorganic salts (NaCl), sugar alcohols (*mannitol and sorbitol*) and non-ionic surfactants in the range to 1%(w/v), .05%-.5% (w/v), 0.1%-10% (w/v), 0.5%-6% (w/v) and 1%-3%. Vukmirovic et al. teach *neutral amino acids (glycine)* at a concentration of 0.5% w/v (pages 3, 8-9, 11, 18 and claims; **applies to claims 1, 3-5, 7 and 9**).

Applicant states that the instant claims have been amended to replace the term "isotonic reagent" with the term "water-soluble inorganic salt". Applicant argues that the presently claimed invention is described in both the instant application and in foreign priority document Korean application KR 10-2003-0037060. Applicant cites pages in the instant application and Korean application for support. Applicant argues that that they

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have claim to a priority date of June 10, 2003. Applicant maintains that the Vukmirovic reference has an effective priority date of WO 2004/006958. Applicant argues that the Vukmirovic reference was filed after the effective priority date of the instant application and therefore is not a proper 102(e) reference.

Applicant's arguments have been fully considered and are found partly persuasive for the following reasons:

A. The Korean document teaches ***water-soluble inorganic salts*** to include **sodium chloride, calcium chloride, and sodium sulfate. The amount of water-insoluble inorganic salts is preferably 0.001 to 0.7% (w/v)**(page 9, line 21-page 10, line 6). The instant specification teaches an example of ***isotonic reagents includes water-soluble inorganic salts and these salts include for example, sodium chloride, calcium chloride, sodium sulfate with a range of 0.001 to 0.7% (w/v)***(page 10, lines 1-7)

In view of the instant amendment ("an isotonic reagent" replaced with "water-soluble inorganic salt", Applicant can rely on foreign priority for support for this limitation.

B. The Korean document teaches ***isotonic reagents*** to include **mannitol, sorbitol, cyclitol and inositol** (page 10, lines 19-24). The Korean document teaches **mannitol in an amount of 1.0%** (page 11, line 20). The Korean document teaches the amount of ***sugar alcohol is preferably 0.1 to 1.0% (w/v)***(page 10, lines 23-24). The Korean document does not have a general disclosure of sugar alcohols. That is to say, the Korean document does not state, "a representative example of sugar alcohols

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include...". This is in contrast to the instant specification, which specifically teaches **sugar alcohols** to include **mannitol, sorbitol, cyclitol and inositol preferably 0.1 to 1.0% (w/v)** (page 9, lines 8-14).

Applicant cannot rely on foreign priority for support for the limitation "**mannitol, sorbitol, cyclitol and inositol in amounts of 0.1 to 1.0% (w/v)**" (i.e. instant claim 1 and instant claim 3) because the Korean document *only* teaches mannitol in an amount of *only* 1.0% **AND** the Korean document fails to teach mannitol as a sugar alcohol.

Applicant cannot rely upon the foreign priority because the invention as claimed in the instant application is not described in foreign priority document Korean application KR 10-2003-0037060. The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.

Conclusion

Claims 1-5, 7, 9-11 are rejected.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to REGINA M. DEBERRY whose telephone number is (571)272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey J. Stucker can be reached on (571) 272-0911. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. M. D./
Examiner, Art Unit 1647
5/12/11

/MARIANNE P ALLEN/
Primary Examiner, Art Unit 1647